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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/068,377	05/08/1998	LAURENCE A. LASKY	P1066P2	2255
7590	06/30/2004			
Ginger R Dreger heller Ehrman White & McAAuliffe LLP 275 Middlefield Road Menlo Park, CA 94025			EXAMINER RAWLINGS, STEPHEN L	
			ART UNIT 1642	PAPER NUMBER

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/068,377

Applicant(s)

LASKY ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2004 and 18 December 2003.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-18 and 24 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 16-18 and 24 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed on April 8, 2004 is acknowledged and has been entered.
2. The amendment filed on December 18, 2003 is acknowledged and has been entered. Claim 24 has been amended.
3. Claims 16-18 and 24 are pending in the application and are currently under prosecution.

Grounds of Objection and Rejection Withdrawn

4. Unless specifically reiterated below, Applicant's amendment filed December 18, 2003 has obviated the grounds of objection and rejection set forth in the previous Office action mailed September 8, 2003.

Priority

5. Applicants have claimed the benefit of the earlier filing date of PCT/US98/01774 filed January 30, 1998, which was given benefit of the earlier filing date of US Application No. 08/938,830 filed September 29, 1997, which was given benefit of the earlier filing date of US Provisional Application No. 60/104,589 filed February 7, 1997. However, because the specifications of these documents to which Applicants have claimed benefit do not disclose a proper and sufficient antecedence to support the language presently recited in claim 24 for the reasons set forth below, Applicants have not been given the claimed benefit. Accordingly, the earliest effective filing date of this application is deemed May 8, 1998.

Claim Rejections – 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 16-18 and 24 are rejected under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, has possession of the claimed invention.

This is a new matter rejection.

Claim 24 recites, “derivable from an antibody-producing cell” and “an epitope within SEQ ID NO:1 of the polypeptide of SEQ ID NO:1”. At page 13 of the amendment filed December 18, 2003, Applicant has stated support for the amendments to the claim can be found at, for example, page 3 (lines 3-5), page 10 (line 15), page 11 (lines 29-39), page 12 (lines 1-6), page 29 (lines 25-39), page 30 (lines 1-24), and elsewhere. However the originally filed specification, including the originally filed claims, does not appear to provide proper and sufficient written support for this language in the instant claims. Regarding the language, “derivable from an antibody-producing cell”, at page 30, the specification discloses preferred myeloma cells are those that support stable high level expression of antibody by the selected antibody-producing cells, but this disclosure fails to provide adequate written support for the language of the instant claim, because the only example of the selected antibody-producing cells are lymphocytes; see page 30, lines 13-15. The disclosure at page 30 therefore does not support the breadth of the instant claim. Regarding the language, “an epitope within SEQ ID NO:1 of the polypeptide of SEQ ID NO:1”, the specification describes the epitopes of short peptides, e.g., FLAG, but does not describe an epitope contained within the polypeptide of SEQ ID NO: 1. Because the language of the claim is not supported by the originally filed specification, the language appears to introduce new matter and thereby violates the written description requirement set forth under 35 USC § 112, first paragraph.

These issues might be resolved if Applicant were to point to particular disclosures in the specification, as originally filed, including the originally filed claims, which are believed to provide the necessary written support for the language of the instant claims.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 24 is rejected under 35 U.S.C. 102(a) as being anticipated by Spencer et al. (*J. Cell. Biol.* 1997 August 25; **138** (4): 845-860), as evidenced by Becker et al. (*FEBS Lett.* 1998; **441** (1): 141-147), for the reason set forth in the previous Office action.

Applicant has traversed this ground of rejection arguing that the instant claims should receive benefit of the claimed priority, such that Spencer et al. is not prior art.

Applicant's argument has been carefully considered but not found persuasive since as explained above, the effective filing date of the instant claims is May 8, 1998.

10. Claims 16, 17, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Sodhi et al. (*Biochemistry and Molecular Biology International* **35**: 559-565, 1995; abstract of record).

Sodhi et al. teaches the use of anti-phosphotyrosine-FITC antibody, a fluorescently labeled and detectable antibody, to study proteins. It is an inherent property of the prior art antibody to specifically bind tyrosine-phosphorylated proteins. In light of the specification, it is clear that an anti-phosphotyrosine monoclonal antibody specifically binds to an epitope contained within the protein of SEQ ID NO: 1.

11. Claims 16-18 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Frackleton et al. (*Journal of Biological Chemistry* **259**: 7909-7915, 1984; abstract of record).

Frackleton et al. teaches the use of an anti-phosphotyrosine monoclonal antibody, which is produced by a hybridoma cell line, to isolate proteins. It is an inherent property of the prior art antibody to specifically bind tyrosine-phosphorylated proteins. In light of the specification, it is clear that an anti-phosphotyrosine monoclonal antibody specifically binds to an epitope contained within the protein of SEQ ID NO: 1.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 16-18 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spencer et al. (*J. Cell. Biol.* 1997 August 25; **138** (4): 845-860) in view of Ackerman (*Human Cell* **1**: 46-53, 1988) and Nakamura et al. (*Cell Struct. Funct.* 1984 June; **9** (2): 167-169) for the reason set forth in the previous Office action.

Applicant has traversed this ground of rejection arguing that the instant claims should receive benefit of the claimed priority, such that Spencer et al. is not prior art.

Applicant's argument has been carefully considered but not found persuasive since as explained above, the effective filing date of the instant claims is May 8, 1998.

14. Claims 16-18 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Database SPTREMBL 23 Accession No. P978144 (01 May 1997) in view of Ackerman (*Human Cell* **1**: 46-53, 1988) and Nakamura et al. (*Cell Struct. Funct.* 1984 June; **9** (2): 167-169) for the reason set forth in the previous Office action.

Applicant has traversed this ground of rejection arguing that the instant claims should receive benefit of the claimed priority, such that Spencer et al. is not prior art.

Applicant's argument has been carefully considered but not found persuasive since as explained above, the effective filing date of the instant claims is May 8, 1998.

Conclusion

15. No claims are allowed.

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16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
June 28, 2004

Phillip Gambel
PHILLIP GAMBEL, PH.D.
PRIMARY EXAMINER
Let's check back
6/28/04